



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2016-0438; FRL-9967-69-OW]

Request for Public Comments to be sent to EPA on Peer Review Materials to Inform the Safe Drinking Water Act Decision Making on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for public comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the release of materials for public comment. These materials will undergo expert peer review in support of EPA's Safe Drinking Water Act decision making for perchlorate. This request is one of two Federal Register notices being published concurrently, seeking public comment on two separate sets of peer review materials. This notice requests comments (to be sent to EPA) on a draft report entitled "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (draft MCLG Approaches Report). The companion notice requests comments (to be sent to EPA's contractor, Versar, Inc.) on an interim list of peer reviewers and draft charge questions.

DATES: Comments must be received by EPA on or before [INSERT DATE 45 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2016-0438 to the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any

information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: For additional information concerning the draft MCLG Approaches Report, please contact Samuel Hernandez at U.S. EPA, Office of Ground Water and Drinking Water, Standards and Risk Management Division, (Mail Code 4607M), 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone: 202-564-1735; or e-mail: Hernandez.Samuel@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information on EPA's Revised Biologically Based Dose-Response (BBDR) Model

As a part of the national primary drinking water regulation (NPDWR) development process for perchlorate, in accordance with the requirements of the Safe Drinking Water Act, in 2012, EPA requested comment from EPA's Science Advisory Board (SAB) prior to proposing an MCLG and a NPDWR for perchlorate. EPA sought guidance on how best to consider and interpret life stage information, epidemiologic and biomonitoring data, physiologically-based pharmacokinetic analyses and the totality of perchlorate health related information to derive a

perchlorate MCLG.

In 2013, the SAB recommended that, “. . . EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon its mode of action rather than the default MCLG approach using the reference dose and specific chemical exposure parameters” (Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate, EPA-SAB-13-004).

Based on the SAB’s recommendations, EPA, with contributions from Food and Drug Administration scientists, developed a biologically based dose response (BBDR) (also known as a PBPK/PD) model, to predict the effects of perchlorate on serum thyroid hormone concentrations in pregnant and lactating women exposed to perchlorate in drinking water and in infants exposed via ingestion of perchlorate in formula or breast milk.

On January 10 and 11, 2017, EPA’s contractor (Versar, Inc.) conducted an independent, scientific peer review of EPA’s draft BBDR model and draft model report. The purpose of the peer review was to provide a documented, independent, and critical review of the draft BBDR model and draft model report and to identify any necessary improvements to the model prior to being finalized. On March 29, 2017, EPA received the final peer review report entitled, “External Peer Review for EPA’s Draft Biologically Based Dose-Response (BBDR) Model and Draft BBDR Model Report for Perchlorate in Drinking Water,” which is available through the EPA docket at <https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0439>.

In developing the draft MCLG Approaches Report, EPA revised the BBDR model to address those peer review recommendations that had the greatest influence on the scientific rigor

of the model and modeling results. Those changes are described in the draft MCLG Approaches Report. EPA will consider other peer review recommendations and public comments in future revisions to the BBDR model and report.

II. Information on EPA’s Draft Approaches to Inform the Derivation of a Perchlorate MCLG

The SAB also recommended that EPA, “utilize a mode of action (MOA) framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts.”

EPA used the modeled thyroid hormone levels to predict potential adverse health effects based on published epidemiology data demonstrating a relationship between changes in thyroid hormone levels and neurodevelopmental effects. This approach involved a focused review of the literature connecting altered thyroid hormone levels to neurodevelopmental outcomes for women in early pregnancy. EPA focused on studies that provided a quantitative description of the relationship between free thyroxine and neurodevelopment in infants and children (e.g., intelligence quotient, verbal and problem solving skills and motor coordination).

EPA will present an array of approaches to inform the derivation of an MCLG for perchlorate for expert peer review. Using the revised BBDR model output, EPA linked statistical relationships derived from five studies to implement the MOA framework linking perchlorate exposure to neurodevelopmental impacts. All five studies assess the relationship between thyroid hormone levels in women in early pregnancy and various neurodevelopmental effects on

children at various ages. Two studies assess the relationship on the IQ of children 5 to 10 years of age, two other studies assess the relationship on Bayley Scales of Infant Development of children 1 to 2 years of age, and a fifth study assesses the relationship on reaction time of children 5 to 6 years of age. An additional approach uses the revised BBDR model output to predict the percent change in the population of hypothyroxinemic (or the low-end of normal thyroid hormone levels) pregnant women due to perchlorate exposure.

III. How to Obtain the Draft MCLG Approaches Report and Revised BBDR Model

EPA's draft report entitled "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" is available electronically and can be accessed using EPA's public docket at <https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0438>. The revised BBDR model code files can be accessed at https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3352518. All written comments must be submitted during the public comment period.

IV. Exclusion for Peer Review Candidates

Important: Anyone wishing to be considered as an expert peer reviewer must not submit comments during the public comment period. Candidates on the interim list not selected for the panel peer review (see companion Peer Review Federal Register notice, published on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]) will be given a limited opportunity to submit

public comments once the final peer reviewers are selected by Versar, Inc., the EPA contractor managing this peer review process.

Dated: September 6, 2017.

Michael H. Shapiro,
Acting Assistant Administrator,
Office of Water.

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